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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,791	04/27/2001	Chihiro Uematsu		7893

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[REDACTED] EXAMINER

TAYLOR, JANELL E

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1634

DATE MAILED: 06/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09 842 791	Applicant(s)	C. Uematsu et al
Examiner	J. Taylor	Group Art Unit	1634

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on \_\_\_\_\_

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1-22 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) 1-22 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other Detailed Action

## Office Action Summary

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 2-7, drawn to a method for assaying DNA fragments in a mixture, classified in class 435, subclass 6.
  - II. Claims 8-9, drawn to primers that comprise plural module sequences in orders varying, composed of 4-6 nucleotides, classified in class 435, subclass 6.
  - III. Claims 10-11, drawn to primers corresponding to the individual groups characteristically comprising a 10-25 nucleotide common nucleotide, a selective sequence of one to three nucleotides, and module sequences of 4-6 nucleotides, classified in class 435, subclass 6.
  - IV. Claims 12-13, drawn to plural primers with different nucleotide sequences used in PCR, wherein the primers comprise different orders of plural module sequences composed of plural nucleotides and the plural primers, classified in class 435, subclass 6.
  - V. Claims 14-16, drawn to plural primer sets of plural primers with different nucleotide sequences for use in PCR, classified in class 435, subclass 6.
  - VI. Claims 17-20, drawn to a method for amplifying nucleic acid comprising preparing a first and second primer with first and second modules, classified in class 435, subclass 91.2.
  - VII. Claims 21-22, drawn to a method for amplifying comprising preparing a plurality of primers and modules with the same melting temperature, classified in class 435, subclass 91.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions are drawn to different products, which have different structures and different functions. Each group is drawn to a primer, however, the primers are comprised of different modules, or components, from each other, and each module, or component, has a different structure, which has a different function, than those found in the other groups.

3. Inventions I and VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to method claims. The methods, however, are for different functions. The method of group I is for assaying DNA fragments in a mixture, while the methods of groups VI-VII are drawn to methods for amplifying. Assaying and amplifying are fundamentally different methods, with different functions. Furthermore, the methods have different steps, which indicates that they have different modes of operation.

4. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of amplification. However, the method of group VI is drawn to preparing certain primers for use, while the method of group VII is drawn to the preparation of a different set of primers (the primers of the two method claims have different requirements). Therefore, the groups have different modes of operation, as well as different functions.

5. Inventions II-V and I, VI, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products are primers. Since the specific sequence of the primers is not disclosed in any of the claims, then the products may be used in different processes (like in assays requiring probes, or in sequencing reactions.) Furthermore, the processes may be carried out using primers that are different from those found in groups II-V.

6. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group VI or VII, and that for groups I and VI-VII is not required for groups II-V, and that for group II is not required for groups II-V, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland whose telephone number is 703-305-0273. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janell Taylor Cleveland  
Examiner  
Art Unit 1634



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600

June 18, 2002